DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 20 2010

Re: PRISTIQ
Patent Nos. 6,673,838 and 7,291,347
Docket Nos.: FDA-2009-E-0084
FDA-2009-E-0086

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 6,673,838 and 7,291,347 filed by Wyeth, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for PRISTIQ (desvenlafaxine sucinate), the human drug product claimed by the patents.

The total length of the regulatory review period for PRISTIQ (desvenlafaxine sucinate) is 2,124 days. Of this time, 1,324 days occurred during the testing phase and 800 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 9, 2002.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 9, 2002.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 22, 2005.

   The applicant claims December 22, 2005, as the date the new drug application (NDA) for PRISTIQ (NDA 21-966) was initially submitted. However, FDA records indicate that the application initially submitted for PRISTIQ was NDA 21-992, and FDA has confirmed that NDA 21-992 was initially submitted on December 22, 2005.

3. The date the application was approved: February 29, 2008.

   FDA has verified the applicant's claim that PRISTIQ was approved on February 29, 2008. However FDA records indicate that it was NDA 21-992 that was approved.

This determination of the regulatory review period by FDA does not take into account the effective date of the patents, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Kevin G. Shaw
Hogan & Hartson, LLP
555 Thirteenth St., NW
Washington, DC 20004